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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,142

11/24/2003

Dan T. Simionescu

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EXAMINER

KHAN, AMINA S

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

12/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,142	SIMIONESCU ET AL.	
	Examiner	Art Unit	
	AMINA KHAN	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/11/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,28-30,32-39,47-49 and 51-55 is/are pending in the application.
- 4a) Of the above claim(s) 30,32-39 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21,24,28,29,48-49, 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in view of applicant's amendments filed on September 11, 2008.
2. Claims 20,21,24,28-30,32-39,47-49 and 51-55 are pending. Claims 1-19, 22,23,25-27,31,40-46 and 50 have been cancelled. Claims 30, 32-39 and 47 have been withdrawn from consideration due to a non-elected invention. Claims 54 and 55 are new. Claims 20,21,29,30,32 and 48 have been amended.
3. The 35 U.S.C. 112 first paragraph rejection of claims 20,21 and 48 is withdrawn in view of applicant's amendments.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 20,21,24,28,29,48,49 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasiaux et al. (WO 01/21228) in view of Nguyen-Thien-Nhon (US 6,001,126).

Tasiaux et al. teach treating bovine pericardium with glutaraldehyde and gallotannic acid (page 35; lines 20-25 and page 36, lines 20-30). Tasiaux et al. further teach that these compounds provide the tissue with calcification resistance and stabilization (page 3 lines 1-5). Tasiaux et al. further teach the aldehyde crosslinks the collagen of the tissue (page 14, line 40 to page 15, line 5). Tasiaux et al. further teach tannic acid may be used to treat the tissue (page 3, lines 15-20), that aortic valves or pericardium may be treated (page 2, lines 20-30) and that these treated tissues are suitable for implants (column 20, lines 39-41). Tasiaux et al. further teach applying the techniques to cardiac valves or tissues (page 15, lines 10-15).

Tasiaux et al. do not teach cross-linked elastin or the concentration of the elastin.

Nguyen-Thien-Nhon teaches bioprosthetic implantable heart valves (column 2, lines 40-50) treated with a fixative or tanning agent such as glutaraldehyde for cross-linking the tissue (column 4, lines 60-67; column 5, lines 1-10) wherein the heart valves possess large amounts of collagen and elastin (column 1, lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the cardiac valves and vessels and aortic valves taught by Tasiaux et al. would incorporate the elastin at the instantly claimed percentages because Nguyen-Thien-Nhon teach these valves possess large amounts of elastin and are conventionally fixed with chemical cross-linking agents such as glutaraldehyde. It would be expected that in the presence of elastin, a cross-linking agent such as tannic acid or glutaraldehyde would obviously provide a cross-linking of the elastin in the tissue. Furthermore, the disclosure of "large amounts of elastin" in the heart valves by

Nguyen-Thien-Nhon would be expected to encompass the at least 30% instantly claimed. Additionally, one of ordinary skill in the art would be motivated to optimize the concentration of elastin to provide enhanced cross-linking of the tissue for enhanced stabilization and anti-calcification benefits of the implant.

6. Claims 20,21,24,28,29,48,49 and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tasiaux et al. (WO 01/21228) in view of Nguyen-Thien-Nhon (US 6,001,126) and further in view of Yang (US 2003/0078659).

Tasiaux et al. and Nguyen-Thien-Nhon are relied upon as described in paragraph 5.

Tasiaux et al. and Nguyen-Thien-Nhon do not explicitly disclose vena cava tissue.

Yang teaches that it is advantageous to make prosthesis from vena cava tissue which has been chemically treated or crosslinked (paragraph 0025).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Tasiaux et al. and Nguyen-Thien-Nhon to incorporate vena cava tissue because Tasiaux et al. teach applying the techniques to cardiac valves or tissues to provide the tissue with calcification resistance and stabilization and Yang teach the desirability of using crosslinked vena cava tissue, a known cardiac tissue, in bioprosthetic implants. Furthermore, the vena cava tissue would obviously incorporate the elastin at the instantly claimed percentages because it would be a property of that type of tissue. Furthermore, the disclosure of "large amounts

of elastin" in the heart valves by Nguyen-Thien-Nhon would be expected to encompass the at least 30% instantly claimed. Additionally, one of ordinary skill in the art would be motivated to optimize the concentration of elastin to provide enhanced cross-linking of the tissue for enhanced stabilization and anti-calcification benefits of the implant.

Response to Arguments

7. Applicant's arguments filed Tasiaux et al. in view of Nguyen-Thien-Nhon have been fully considered but they are not persuasive. The examiner asserts that Tasiaux teach treating all cardiac tissue and vessels, and this disclosure along with the teaching of Nguyen-Thien-Nhon to treat tissues with high elastin contents would encompass the 30% limitation. Applicant acknowledges that aortic wall tissue is encompassed by these teachings and would possess greater than 30% elastin. Accordingly, the rejections are maintained.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMINA KHAN whose telephone number is (571)272-5573. The examiner can normally be reached on Monday through Friday, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorna M Douyon/
Primary Examiner, Art Unit 1796

/Amina Khan/
Examiner, Art Unit 1796
December 7, 2008